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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,372	01/25/2002	Kenneth E. Kadziauskas	2783	4335

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EXAMINER	
FOREMAN, JONATHAN M	
ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 11/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/073,372	KADZIAUSKAS ET AL.	
	Examin r	Art Unit	
	Jonathan ML Foreman	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,017,316 to Ritchart et al.

In reference to claims 1, 3, 10 and 11, Ritchart et al. discloses a surgical apparatus as claimed by applicant including: a hollow needle (Col. 5, lines 20 – 21) having a port for enabling tissue entry into the needle lumen (Col. 5, lines 24 – 28); a cutting blade disposed within the hollow needle for severing tissue (Col. 5, line 23); a driver, connected to the cutting blade, for moving the blade between a first and second position, the tissue entering the needle being severed as the blade moves between the first and second position (Col. 6, lines 25 – 62); a vacuum source for causing tissue entry into the needle lumen trough the port and for aspirating severed tissue (Col. 6, lines 54 – 58); and a controller, including a valve for controlling vacuum communication between the vacuum source and the needle lumen, for coordinating vacuum and blade movement so that vacuum is provided to the needle lumen when the blade is in the first position and during the severing of the tissue by the blade and reducing vacuum to the needle lumen before moving the blade from the second position to the first position. Ritchart et al. discloses stopping the vacuum (Col. 6, line 21 – Col. 8, line 11.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 2 and 7 – 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,017,316 to Ritchart et al. in view of U.S. Patent No. 5,685,320 to Zimmon et al.

In reference to claims 2 and 7 – 9, Ritchart et al. discloses applying vacuum to the tissue to bring the tissue into the port, and moving the blade to sever tissue (Col. 6, lines 54 – 58). However, Ritchart et al. fails to disclose regulating the vacuum applied to the tissue, nor does Ritchart et al. disclose regulating the position of the blade to control the amount of tissue severed during blade movement. Zimmon et al. teaches that the size of a biopsy sample can be changed based on the amount of vacuum or suction, and the area of the opening that receives the sample (Col. 4, lines 20 – 28). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Ritchart et al. to include the steps of regulating the vacuum applied to the tissue and regulating the position of the blade to allow for more or less area to be open to the tissue in order to modify the size of the biopsy sample as taught by Zimmon et al.

5. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,017,316 to Ritchart et al. in view of U.S. Patent No. 6,120,462 to Hibner et al.

In reference to claims 4 and 6, the amount of tissue severed is related to the movement of the blade as disclosed by Ritchart et al. However, Ritchart et al. fails to disclose regulating the speed of movement of the blade. Hibner et al. teaches a biopsy device wherein the speed the cutter is

regulated (Col. 4, lines 47 – 56). It would have been obvious to one having ordinary skill in the art at the time the invention was made to regulate the speed of the blade as disclosed by Ritchart et al. in order to maintain the speed of the blade in an optimal range while translating through tissue (Col. 2, lines 51 – 53).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,017,316 to Ritchart et al. in view of U.S. Patent No. 5,685,320 to Zimmon et al. as applied to claim 2 above and further in view of U.S. Patent No. 6,120,462 to Hibner et al.

In reference to claim 5, the amount of tissue severed is related to the movement of the blade as disclosed by Ritchart et al. However, Ritchart et al. fails to disclose regulating the speed of movement of the blade. Hibner et al. teaches a biopsy device wherein the speed the cutter is regulated (Col. 4, lines 47 – 56). It would have been obvious to one having ordinary skill in the art at the time the invention was made to regulate the speed of the blade as disclosed by Ritchart et al. in order to maintain the speed of the blade in an optimal range while translating through tissue (Col. 2, lines 51 – 53).

Response to Arguments

Applicant's arguments filed 8/18/03 have been fully considered but they are not persuasive. Applicant has asserted that Ritchart et al. fails to disclose a vacuum source in communication with the needle for evacuation or aspirating severed tissue from the needle. However, the examiner disagrees. Ritchart et al. discloses a vacuum source in communication with the needle (16) used during the evacuation of severed tissue from the needle (Col. 7, lines 10 – 15). Applicant has pointed out that Ritchart et al. states that "the high vacuum pressure applied through the cutter lumen 20 from the proximal port 50 functions to retain the tissue specimen in the lumen during the ensuing transport of the cutter and specimen proximally (i.e. proximally through the needle) to a

suitable tissue receptacle in a tissue chamber 58". Claim 1 states, "evacuation severed tissue from the needle by vacuum". The vacuum as disclosed by Ritchart et al. is clearly used in the evacuation of the severed tissue. The limitations "for aspirating severed tissue through the lumen" and "for aspiration of severed tissue through the lumen" found in claims 10 and 11 respectively, are functional limitations related to the vacuum source. It is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. ***In re Pearson***, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); ***In re Casey***, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); ***In re Otto***, 312 F.2d 937, 136 USPQ 458 (CCPA 1963). Where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function. ***In re Ludtke***, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). In addition, where there is reason to believe that such functional limitation may be an inherent characteristic of the prior art reference, Applicant is required to prove that the subject matter shown in the prior art reference does not possess the characteristic relied upon. ***In re Spada***, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); ***In re King***, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); ***In re Ludtke***, 441 F.2d 664, 169 USPQ 566 (CCPA 1971). In the present case, the vacuum source connected to the needle (16) and supplying a vacuum to the needle (Col. 5, lines 27 – 30) disclosed by Ritchart et al. is capable of aspirating severed tissue through the lumen of the needle.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-872-9306 for regular communications and (703)-872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.

JMLF
November 4, 2003

MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700